DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 23, 2015

Medentika GmbH
c/o Ms. Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K150203
Trade/Device Name: Medentika CAD/CAM Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 23, 2015
Received: September 25, 2015

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150203

Device Name

Medentika CAD/CAM Abutments

Indications for Use *(Describe)*

Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Series	Implant Diameter (mm)	Platform Diameter (mm)
Nobel Biocare Replace™ Select	E	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive™	F	3.5, 4.3, 5.0	3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite® Certain®	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
Biomet 3i Osseotite®	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
Nobel Biocare Brånemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
Straumann Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
Straumann Standard	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
Zimmer Tapered Screw-vent®	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Astra Tech OsseoSpeed™	S	3.5, 4.0, 4.5, 5.0	3.5, 4.0, 4.5, 5.0
Dentsply Friadent® Frialit/XiVE®	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
Dentsply Friadent® Ankylos®	Y	3.5, 4.5, 5.5, 7.0	3.5, 4.5, 5.5, 7.0

Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150203

Device Name

Medentika CAD/CAM Abutments

Indications for Use *(Describe)*

Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Series	Implant Diameter (mm)	Platform Diameter (mm)
Nobel Biocare Replace™ Select	E	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive™	F	3.0, 3.5, 4.3, 5.0	3.0, 3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite® Certain®	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
Biomet 3i Osseotite®	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
Nobel Biocare Brånemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
Straumann Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
Straumann Standard	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
Zimmer Tapered Screw-vent®	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Astra Tech OsseoSpeed™	S	3.0, 3.5, 4.0, 4.5, 5.0	3.0, 3.5, 4.0, 4.5, 5.0
Dentsply Friadent® Frialit/XiVE®	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5

Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
Medentika GmbH Medentika
CAD/CAM Abutments
K150203

October 22, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	Medentika GmbH Hammweg 8-10 76549 Hügelsheim, Germany Telephone +49 (0)7229-69912-0 Fax +49 (0)7229-69912-20
Official Contact	Gerhard Polzer Head of Quality Management / Regulatory Affairs
Representative/Consultant	Linda K. Schulz Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: LSchulz@paxmed.com FLarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Medentika CAD/CAM Abutments
Common Name	Endosseous dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATES

The primary predicate for the Medentika TiBase is K120822, Straumann® CARES® Variobase™ Abutment. The primary predicate for the Medentika PreFace is K052272, Straumann C.A.R.E.S. Titanium Abutment.

Reference Predicates:

K111935	Ti-Base for individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges
K082545	Straumann® NN CARES® Titanium Abutment and NN CARES® Ceramic Abutment
K083192	Inclusive® Titanium Abutment Blanks
K073713	Blue Sky Bio Dental Implant System
K120822	Straumann® CARES® Variobase™ Abutments
K111935	Ti-Base for individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges
K052272	Straumann C.A.R.E.S. Titanium Abutment
K082545	Straumann® NN CARES® Titanium Abutment and NN CARES Ceramic Abutment
K083192	Inclusive® Titanium Abutment Blanks
K073713	Blue Sky Bio Dental Implant System
K020646	Replace™ HA Coated Implant
K071370	NobelActive™ Internal Connection Implant
K102436	NobelActive™ 3.0
K063341	3i OSSEOTITE® Certain® Dental Implants
K063286	OSSEOTITE® Dental Implants
K022562	Various Brånemark System Implants – Immediate Function Indication
K062129	P.004 Implants
K130222	Straumann® Dental Implant System SLActive and Roxoid Product Families
K061410	Zimmer Dental Implant System
K101732	Astra Tech Implant System
K073075	FRIADENT® Implant Systems
K041509	ANKYLOS® Dental Implant System

DEVICE DESCRIPTION

The subject device includes two CAD/CAM abutment designs, the Medentika TiBase and the Medentika PreFace. The TiBase is a two-piece abutment used as a base when fabricating a zirconia superstructure and the PreFace is an abutment used in fabricating a full patient-specific abutment in titanium alloy. Both abutment designs are provided non-sterile and are intended to be sterilized by the clinician. Medentika Preface Abutment is available in diameters 3.0 mm to 7.0 mm. Medentika TiBase Abutment is available in diameters 3.25 mm to 7.0 mm. The specific diameters for each Series coordinate with the compatible implant systems and sizes listed below.

TiBase is available in two post designs. TiBase Generation 1 has a conically shaped post that is 4.0 mm high and TiBase Generation 2 has a parallel walled post shape that is 5.5 mm high. PreFace is available in one cylinder height of 20 mm. The maximum angle for abutments fabricated using TiBase or PreFace is 30°, the maximum gingival height is 6 mm and the minimum post height is 4 mm.

Medentika CAD/CAM Abutments are compatible with eleven dental implant systems. Each Medentika abutment series has a precision implant/abutment interface corresponding to the implant system predicate for that series. Compatible sizes are as follows:

Nobel Biocare Replace™ Select	E-Series	3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive™	F-Series	3.0, 3.5, 4.3, 5.0 (3.0 PreFace Only)
Biomet 3i Osseotite® Certain®	H-Series	3.25, 4.0, 5.0
Biomet 3i Osseotite®	I-Series	3.25, 3.75, 4.0, 5.0
Nobel Biocare Brånemark	K-Series	3.3, 3.75, 4.0, 5.0
Straumann Bone Level	L-Series	3.3, 4.1, 4.8
Straumann Standard	N-Series	3.3, 4.1, 4.8
Zimmer Tapered Screw-Vent®	R-Series	3.3, 3.7, 4.1, 4.7, 6.0
Astra Tech OsseoSpeed™	S-Series	3.0, 3.5/4.0, 4.5/5.0 (3.0 PreFace Only)
Dentsply Friadent® Frialit/XiVE®	T-Series	3.4, 3.8, 4.5, 5.5
Dentsply Friadent® Ankylos®	Y-Series	3.5, 4.5, 5.5, 7.0 (Y-Series TiBase Only)

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included engineering analysis and dimensional analysis for determination of compatibility using critical dimension measurements of the original manufacturers' components, static and dynamic compression-bending testing for the Medentika TiBase and Medentika PreFace according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*, sterilization validation according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-*2 Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1* to demonstrate an SAL of 10^{-6}, and biocompatibility testing for cytotoxicity according to ISO 10993-5 *Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity.* All materials conform to FDA recognized standards and no further biocompatibility testing was performed. The performance data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

INTENDED USE

TiBase

Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Series	Implant Diameter (mm)	Platform Diameter (mm)
Nobel Biocare Replace™ Select	E	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive™	F	3.5, 4.3, 5.0	3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite® Certain®	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
Biomet 3i Osseotite®	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
Nobel Biocare Brånemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
Straumann Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
Straumann Standard	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
Zimmer Tapered Screw-vent®	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Astra Tech OsseoSpeed™	S	3.5, 4.0, 4.5, 5.0	3.5, 4.0, 4.5, 5.0
Dentsply Friadent® Frialit/XiVE®	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
Dentsply Friadent® Ankylos®	Y	3.5, 4.5, 5.5, 7.0	3.5, 4.5, 5.5, 7.0

Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.

PreFace

Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Series	Implant Diameter (mm)	Platform Diameter (mm)
Nobel Biocare Replace™ Select	E	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive™	F	3.0, 3.5, 4.3, 5.0	3.0, 3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite® Certain®	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
Biomet 3i Osseotite®	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
Nobel Biocare Brånemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
Straumann Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
Straumann Standard	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
Zimmer Tapered Screw-vent®	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Astra Tech OsseoSpeed™	S	3.0, 3.5, 4.0, 4.5, 5.0	3.0, 3.5, 4.0, 4.5, 5.0
Dentsply Friadent® Frialit/XiVE®	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5

Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.

EQUIVALENCE TO MARKETED DEVICE

Medentika CAD/CAM Abutments are compatible with eleven dental implant systems. Each Medentika abutment series has an implant/abutment interface corresponding to the implant system predicate for that series.

<table>
<tr><th></th><th>Indications for Use</th></tr>
<tr><td>Subject Device</td><td></td></tr>
<tr><td>Medentika GmbH

Medentika CAD/CAM Abutments</td><td>
Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.5, 4.3, 5.0</td><td>3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
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<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Dentsply Friadent® Ankylos®</td><td>Y</td><td>3.5, 4.5, 5.5, 7.0</td><td>3.5, 4.5, 5.5, 7.0</td></tr>
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Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.
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<tr><td>Medentika GmbH

Medentika CAD/CAM Abutments</td><td>
Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
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<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
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<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
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<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>
Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.
</td></tr>
</table>

Predicate Devices	
Institut Straumann AG Straumann® CARES® Variobase ™ Abutment K120822	The Straumann® CARES® Variobase ™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase ™ Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crowns and bridges. Straumann® CARES® Variobase ™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. The Straumann® CARES® Variobase ™ Coping polycon® ae in combination with the Straumann® Variobase ™ Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.
Straumann USA Straumann C.A.R.E.S. Titanium Abutment K052272	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Titanium Abutment is indicated for cemented restorations. The abutment can be used in single tooth replacements and multiple tooth restorations.

The specific language of the Indications for Use Statement is not identical. However, the subject device and corresponding primary predicates are all abutments intended for use with endosseous dental implants for support of single-tooth or multiple-tooth restorations in the upper or lower arch, and therefore, have the same intended use.

Summary: Table of Substantial Equivalence – Abutment Design

	Subject Device	**Primary Predicate Devices**	
	Medentika GmbH Medentika CAD/CAM Abutments	Institut Straumann AG Straumann® CARES® Variobase™ Abutment K120822	Straumann USA Straumann C.A.R.E.S. Titanium Abutment K052272
Design			
Abutment Design	Titanium Base, CAD/CAM Blank	Titanium Base	CAD/CAM Blank
Prosthesis Attachment	Cement-retained	Cement-retained	Cement-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment Diameter (mm)	3.0 – 7.0	3.3 - 6.5	3.3 - 6.5
Abutment Angle	Up to 30°	Up to 30°	Up to 30°
Abutment/ Implant Interface	Indexed, non-indexed	Indexed, non-indexed	Indexed, non-indexed

	Subject Device	Primary Predicate Devices	
	Medentika GmbH Medentika CAD/CAM Abutments	Institut Straumann AG Straumann® CARES® Variobase™ Abutment K120822	Straumann USA Straumann C.A.R.E.S. Titanium Abutment K052272
Material			
Abutment	Titanium Alloy	Titanium Alloy	Titanium Alloy
Screw	Titanium Alloy	Titanium Alloy	Titanium Alloy
Sterility			
Abutment	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile
Screw	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile

CONCLUSION

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is to be sterilized using the same processes.